NATIONAL INSTITUTES OF HEALTH
ANIMAL STUDY PROPOSAL

(See NIH Manual 3040-2)

Leave Blank
PROPOSAL # _____
APPROVAL DATE _____
EXPIRATION DATE _____

A. ADMINISTRATIVE DATA:

Institute or Center_____

Principal Investigator_____

Building/Room_____E-Mail_____Telephone_____FAX_____
Emergency Treatment and Animal Care instructions shall be provided on the attached form at the end of this document.

Division, Laboratory, or Branch_____

Project Title_____

_____

Initial Submission [ ] Renewal [ ] or Modification [ ] of Proposal Number_____
List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e., Co-investigator(s)): A brief summary of the training and/or experience for procedures each individual will be expected to perform in this ASP must be documented and available to the ACUC. The name(s) of the supervisor, mentor, or trainer who will provide assurance each individual is/has achieved proficiency in those procedures shall be included in that documentation.

B. ANIMAL REQUIREMENTS:

Species_____Age/Weight/Size_____Sex_____

Stock or Strain_____

Source(s)_____Holding Location(s)_____

Animal Procedure Location(s)_____

Estimated Number of Animals:

_____ _____ _____ =_____
Year 1 Year 2 Year 3 TOTAL

C. TRANSPORTATION: Transportation of animals must conform to all NIH and Facility guidelines/policies. If animals will be transported between facilities, describe the methods and containment to be utilized. If animals will be transported within the Clinical Center, also include the route and elevator(s) to be utilized.

D. STUDY OBJECTIVES: Provide no more than a 300 word summary of the objectives of this work. Why is this work important/interesting? How might this work benefit humans and/or animals? This should be written so that a non-scientist can easily understand it. Please eliminate or minimize abbreviations, technical terms, and jargon. Where they are necessary, they should be defined.

E. RATIONALE FOR ANIMAL USE: 1) Explain your rationale for animal use. 2) Justify the appropriateness of the species selected. 3) Justify the number of animals to be used. **(Use additional sheets if necessary.)**

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: Briefly explain the experimental design and specify all animal procedures. This description should allow the ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Specifically address the following: (Use additional sheets if necessary.)

- **Injections or Inoculations** (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules)
- **Blood Withdrawals** (volume, frequency, withdrawal sites, and methodology)
- **Minor surgical procedures** (that do not invade a body cavity)
- **Non-Survival Surgical Procedures** (Provide details of major survival surgical procedures in Section G.)
- **Radiation** (dosage and schedule)
- **Methods of Restraint** (e.g., restraint chairs, collars, vests, harnesses, slings, etc.)
- **Animal Identification Methods** (e.g., ear tags, tattoos, collar, cage card, etc.)
- **Other Procedures** (e.g., survival studies, tail biopsies, etc.)
- **Potentially Painful or Distressful Effects**, if any, the animals are expected to experience (e.g., pain or distress, ascites production, etc.) For Column E studies provide: 1) a description of the procedure(s) producing pain and/or distress; 2) scientific justification why pain and/or distress can not be relieved.
- **Experimental Endpoint Criteria** (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.

G. MAJOR SURVIVAL SURGERY - If proposed, complete the following: None ____

1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized.
   (Use additional sheets if necessary):

2. Who will perform surgery and what are their qualifications and/or experience?

3. Where will surgery be performed, Building and Room?_____

4. Describe post-operative care required, including consideration of the use of post-operative analgesics, and identify the responsible individual:

5. Has major survival surgery been performed on any animal prior to being placed on this study? Y/N_____
   If yes, please explain:

6. Will more than one major survival surgery be performed on an animal while on this study? Y/N._____
   If yes, please justify:

H. RECORDING PAIN OR DISTRESS CATEGORY - *The ACUC is responsible for applying U.S. Government Principle IV. contained in Appendix 3: Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.* Check the appropriate category(ies)and indicate the approximate number of animals in each. Sum(s) should equal total from Section B.

IF ANIMALS ARE INDICATED IN COLUMN E, A SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE USE OF ANESTHETICS, ANALGESICS, SEDATIVES OR TRANQUILIZERS DURING AND/OR FOLLOWING PAINFUL OR DISTRESSFUL PROCEDURES IS CONTRAINDICATED. FOR USDA REGULATED SPECIES, PLEASE COMPLETE THE EXPLANATION FOR COLUMN E LISTINGS FORM AT THE END OF THIS DOCUMENT. THIS FORM WILL ACCOMPANY THE NIH ANNUAL REPORT TO THE USDA. FOR ALL OTHER SPECIES, THE JUSTIFICATION FOR SUCH STUDIES MUST BE PROVIDED IN SECTION F. NOTE: THIS COLUMN E FORM, AND ANY ATTACHMENTS, e.g., THE ASP, ARE SUBJECT TO THE FREEDOM OF INFORMATION ACT.

NUMBER OF ANIMALS USED EACH YEAR

	Year 1	Year 2	Year 3
[ ] **USDA Column C** - Minimal, Transient, or No Pain or Distress	_____	_____	_____
[ ] **USDA Column D** - Pain or Distress Relieved By Appropriate Measures	_____	_____	_____
[ ] **USDA Column E** - Unrelieved Pain or Distress	_____	_____	_____

Describe your consideration of alternatives to procedures listed for Column D and E that may cause more than momentary or slight pain or distress to the animals, and your determination that alternatives were not available. [Note: Principal investigators must certify in paragraph N.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether it is relieved or not.] Delineate the methods and sources used in the search below. **Database references must include the databases (2 or more) searched, the date of the search, period covered, and keywords used:**

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION - For animals indicated in Section H, Column D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and schedule of administration. None ____

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: Indicate the proposed method, and if a chemical agent is used, specify the dosage and route of administration. If the method(s) of euthanasia include those not recommended by the AVMA Panel Report on Euthanasia, provide justification why such methods must be used. Indicate the method of carcass disposal if not as MPW. None ____

K. HAZARDOUS AGENTS:

Use of hazardous agents requires the approval of an IC safety specialist. Registration Documents for the use of recombinant DNA or potential human pathogens may be attached at the discretion of the ACUC. None ____

	YES [ ] NO [ ] List Agents and Registration Document Number (If Applicable)
1. Radionuclides	_____
2. Biological Agent	_____
3. Hazardous Chemical or Drugs	_____
4. Recombinant DNA	_____

Study conducted at Animal Biosafety Level: _____

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Use of volatile anesthetics requires a description of scavenging methods used. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity.

Additional safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS (e.g., cell lines, antiserum, etc.): None ____

1. Specify Material_____
2. Source_____ Material Sterile or Attenuated _____Yes _____No
3. If derived from rodents, has the material been MAP/RAP/HAP/PCR tested? _____Yes (Attach copy of results) No_____
4. I certify that the MAP/RAP/HAP/PCR tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____ Initials of Principal Investigator

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY - List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.). Include justification for exemption from participation in the environmental enrichment plan for nonhuman primates or exercise for dogs. None ____

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS:

1. I certify that I have attended an approved NIH investigator training course.
   Year of Course Attendance:_____ Year(s) of Refresher Training: _____

2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.

3. I certify that all individuals working on this proposal who have animal contact are participating in the NIH Animal Exposure Program (or equivalent, as applicable, for contract personnel).

4. I certify that the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal, have attended the course "Using Animals in Intramural Research: Guidelines for Animal Users" will complete refresher training as required, and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); procedures for reporting animal welfare concerns. I further certify that I am responsible for the professional conduct of all personnel listed in Section A.

5. **FOR ALL COLUMN D AND COLUMN E PROPOSALS (see section H):** I certify that I have reviewed the pertinent scientific literature and the sources and/or databases (2 or more) **as noted in section H,** and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.

6. I will obtain approval from the ACUC before initiating any significant changes in this study (See PM 3040-2, F.4.d.).

Principal Investigator: Signature_____Date_____

O. CONCURRENCES: PROPOSAL NUMBER _____ (LEAVE BLANK)

Laboratory/Branch Chief: certification of review and approval on the basis of scientific merit.
Scientific Director's signature required for proposals submitted by a Laboratory or Branch Chief

Name_____Signature_____Date_____

Safety Representative: certification of review and concurrence (Required of all studies utilizing hazardous agents)

Name_____Signature_____Date_____

Facility Manager: certification of resource capability in the indicated facility to support the proposed study

Facility_____Name_____Signature_____Date_____

Facility_____Name_____Signature_____Date_____

Facility_____Name_____Signature_____Date_____

Facility_____Name_____Signature_____Date_____

COMMENTS:

Facility Veterinarian: certification of review

Name_____ Signature _____Date_____

Attending Veterinarian: certification of Review

Name_____Signature_____Date_____

P. FINAL APPROVAL:

Certification of review and approval by the _____ Animal Care and Use Committee Chairperson

Chairperson_____Signature_____Date_____

Column E Explanation Form For Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study. _____**

3. **Species (common name) of animals used in this study. _____**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected. (From ASP Section F)**

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** ***(from ASP, Section F)***

Information below will NOT be forwarded to USDA as part of the Annual Report

IC _____ ASP Number _____ ASP Title_____ Date _____

INSTRUCTIONS FOR EMERGENCY ANIMAL TREATMENT AND CARE

Principal Investigator: _____ Date form completed: _____
Protocol Number: _____
Office Phone: _____
Home Phone: _____

Protocol Title: _____

Use a separate form if ***care is different*** for each species

Species: _____ **Species**: _____
Species: _____ **Species**: _____

Animal Housing Location: Bldg _____
Use separate form if care differs by location
Bldg _____
Bldg _____

List of Procedures:
(surgery, tumor implant, catheter) _____

Primary Point of Contact (P.O.C.) in Case of Emergency:
Work Tel: _____ **Home Tel**: _____ **Pager or Cell #**: _____

Alternate Point of Contact in Case of Emergency:
Work Tel: _____ **Home Tel**: _____ **Pager or Cell #**: _____

Potential or Expected Complications: _____
_____

Circumstances Requiring Contact: _____

Treatment (indicate appropriate response):
Treatment determined by **veterinarian**: [ ] Yes [ ] No
If **NO**, specify **restrictions** as follows: _____
Specific treatment as follows: _____
What **drugs** are **contraindicated**? _____

Criteria for **Euthanasia** (indicate appropriate response)
At Vet discretion if poor condition, severe pain or distress: [ ] Yes [ ] No
If NO, specify treatments **or** restrictions: _____
_____

- Notify P.O.C. *[ ] Yes [ ] No
- Requested **euthanasia agent** and **route of administration**: _____
- Specific **criteria** for **euthanasia**: _____

If Euthanasia is performed or animals are found dead:

a. Contact P.O.C.	[ ] Yes	[ ] No
b. Refrigerate carcass	[ ] Yes	[ ] No
c. Dispose of carcass	[ ] Yes	[ ] No
d. Submit to DVR for necropsy	[ ] Yes	[ ] No

CAN number to use for submission: _____

Additional Comments: _____

Principal Investigator: _____
Signature Date

*** The veterinarian will take the appropriate action in an emergency if no response from the PI/POC is received within 30 minutes after an attempt at notification is made.**